



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : David W. Wynn et al.

Serial No. : 10/697,546 Art Unit:

Filed : October 30, 2003 Examiner:

For : CONTROLLED RELEASE ANALGESIC SUSPENSIONS

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9 Feb 2004

(Date of Deposit)

Michele G. Mangini

(Name of applicant, assignee, or Registered Representative)

A handwritten signature in black ink, appearing to read "Michele G. Mangini".

(Signature)

9 Feb 2004

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:

- Statement in Accordance with §1.97(e)  
(attached); or
- Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- Statement in Accordance with §1.97(e)  
(attached); or

Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the

national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a) (2) (i)).

There are no listed references which are not in the English language.

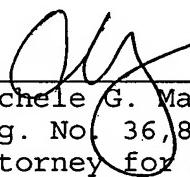
The relevance of those listed references which are not in the English language is as follows:

Attached are copies of search report(s) from related PCT Patent Application No. PCT/US03/08846 (Atty. Docket MCP-325 PCT), which is listed on the attached Submission Under MPEP 609D.

Attached are the non-published pending patent Application Nos. 10/697,840 (Atty. Docket MCP-5021) and 10/393,755 (Atty. Docket MCP-325), which may be deemed relevant and are listed on the attached Submission Under MPEP 609D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP5015/MGM. This form is submitted in triplicate.

Respectfully submitted,

  
\_\_\_\_\_  
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Reg. No. 36,806  
Attorney for Applicants

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DATED: *April 2004*



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,374,659		Gowan, Jr.	12-20-1994	
		4,788,220		Mody et al.	11-29-1988	
		4,975,465		Motola et al.	12-04-1990	
		5,183,829		Caldwell	2-02-1993	
		5,527,545		Santus et al.	6-18-1996	
		4,221,778		Raghunathan	9-09-1980	
		4,847,077		Raghunathan	7-11-1989	
		6,001,392		Wen et al.	12-14-1999	
		4,906,478		Valentine et al.	3-06-1990	
		5,275,822		Valentine et al.	1-04-1994	
		6,103,260		Luber et al.	8-15-2000	
		4,279,926		Bruzzese et al.	7-21-1981	

### FOREIGN PATENT DOCUMENTS

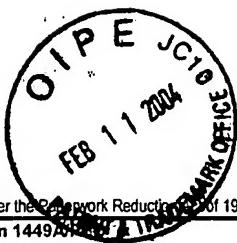
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		✓ WO	96/01628	A1	Recordatia S.A. Chemical and Pharmaceutical Company	1-25-1996		
		✓ WO	97/41839	A1	F.H. Faulding & Co. Limited	11-13-1997		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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<i>Application Number</i>	10/697,546
<i>Filing Date</i>	October 30, 2003
<i>First Named Inventor</i>	Wynn et al.
<i>Group Art Unit</i>	
<i>Examiner Name</i>	
<i>Attorney Docket Number</i>	MCP-5015

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		4,873,231		Smith	10-10-1989	
		5,424,075		Daher et al.	6-13-1995	
		5,510,385		Stroppolo et al.	4-23-1996	
		5,374,659		Gowan, Jr.	12-20-1994	
		5,621,005		Gowan, Jr.	4-15-1997	
		5,409,907		Blase et al.	4-25-1995	
		4,752,580		Downs	6-21-1988	
		3,485,719		Rogovin	12-23-1969	
		2002/0031552	A1	McTeigue et al.	3-14-2002	
		6,197,347	B1	Jan et al.	3-06-2001	
		4,762,709		Sheumaker	8-09-1988	
		4,859,461		Chow et al.	8-22-1989	

## FOREIGN PATENT DOCUMENTS

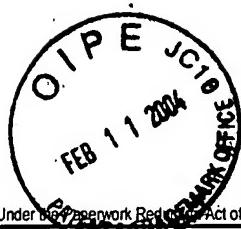
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Sheet 3 of 3

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<i>First Named Inventor</i>	Wynn et al.
<i>Group Art Unit</i>	
<i>Examiner Name</i>	
<i>Attorney Docket Number</i>	MCP-5015

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	<input checked="" type="checkbox"/>	Kameer, B., et al., Ann. Int. Med. 82, pp. 202-209 (1977)	
	<input checked="" type="checkbox"/>	USP 23 (1995) pp. 786	
	<input checked="" type="checkbox"/>	USP 24, 2000 Version, 19-20 and 856-857 (1999)	
	<input checked="" type="checkbox"/>	Lieberman, Herbert A. and Lachman, Leon, "Pharmaceutical Dosage Forms: Tablets, Volume 3, pp. 73-117 and 119-221 (1982)	
	<input checked="" type="checkbox"/>	Selby, Chitrali et al., "Development and in vitro evaluation of multiparticulate sustained release formulation of diltizem hydrochloride using ethylcellulose and cellulose acetate phthalate," Indian Drugs 35(4) April 1998, pp. 195-199	
	<input checked="" type="checkbox"/>	Walter, K., et al., "Pharmacokinetics of ibuprofen following a single administration of a suspension containing enteric coated microcapsules." Arzneim-Forsch/ Drug Res. 45 (II), Nr. 8 (1995), pp. 886-890	
	<input checked="" type="checkbox"/>	Kurumaddail, K.R. et al., "Preparation and evaluation of sustained release ibuprofen beads," Drug Development and Industrial Pharmacy, 20(17), (1994) pp. 2659-2669	
	<input checked="" type="checkbox"/>	BELLAMY N. (Reprint) ET. AL: "A comparative-analysis of two dosing strategies of Flurbiprofen in Rheumatoid-Arthritis-An Application of Sequential Trial Design" Clinical and Investigative Medicine-Medecine Clinique ET Experimentale, (1988) Vol. 11, No. 6, PP. 441-445, XP00901716	
	<input checked="" type="checkbox"/>	BLACK, P. ET. AL.: "A randomized, double-blind, placebo-controlled comparison of the analgesic efficacy, onset of action, and tolerability of ibuprofen arginate and ibuprofen in postoperative dental pain" CLINICAL THERAPEUTICS, Vol. 24, No. 7, 2002, pages 1072-1089, XP002254117	
	<input checked="" type="checkbox"/>	GREBE, W. ET. AL.: "A multicenter, randomized, double-blind, double-dummy, placebo-and active-controlled, parallel-group comparison of diclofenac-K and ibuprofen for the treatment of adults with influenza-like symptoms" CLINICAL THERAPEUTICS, Vol. 25, No. 2, February 2003 (2003-02), pages 444-458, XP001155030	
	<input checked="" type="checkbox"/>	MEHLISCH, D.R.: "Ketoprofen, ibuprofen and placebo in the treatment of primary dysmenorrhea: a double-blind crossover comparison" J. Clin Pharmacol., Vol. 29, No.12, December 1988 (1988-12), pages s29-33, XP009017179	
	<input checked="" type="checkbox"/>	MEHLISCH, D.R.: "Double-blind crossover comparison of ketoprofen, naproxen, and placebo patients with primary dysmenorrhea" CLINICAL THERAPEUTICS, Vol 12, No 5, 1990, pages 398-409, XP009017199	
	<input checked="" type="checkbox"/>	PALMISANO, G. P. ET AL: " Double-blind crossover comparison of ketoprofen, ibuprofen, and placebo in the treatment of patients with primary dysmenorrhea" ADVANCES IN THERAPY, VOL. 5, NO. 4, 1988, pages 128-137 XP009017375	

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SUBMISSION UNDER MPEP 609 D

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Page 1 of 1		Attorney Docket Number	MCP-5015

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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